

**Department of Veterans Affairs
National Research Advisory Council (NRAC)
July 14, 2008
1722 Eye Street NW, Washington, DC
Garden Level Conference Room (GL 20)**

Members present:

Marie Bernard, MD, Chair
Robert Kelch, MD
Col. Aaron Butler, USMC, Ret.
Dudley Childress, PhD
David Korn, MD
Albert Reese, MD, PhD, MBA

OEF/OIF Subcommittee Consultants:

Stephen Waxman, MD, PhD
Joseph Czerniecki, MD

Guest Presenter:

George Wittenberg, MD, PhD, PhD

VA Staff:

David Atkins, MD
Gina Clemons
Lynn Cates, MD
Patricia Dorn, PhD
Seth Eisen, MD, MSc
Jay Freedman, PhD
William Goldberg, PhD
Sandra Isaacson
Joel Kupersmith, MD
Timothy O'Leary, MD, PhD
Alex Ommaya, PhD
Cheryl Oros, PhD
Ron Przygodzki, MD
Michael Selzer, MD, PhD

Guest:

Barbara West, National Association of Veterans' Research and Education
Foundations (NAVREF)

The meeting was called to order by Dr. Bernard at 8:30 a.m. followed by the attendees introducing themselves. NRAC members were asked to review the minutes from the last meeting and approved them unanimously.

Report from CRADO –Dr. Kupersmith:

Dr. Kupersmith gave a brief overview of events since the last NRAC meeting including: the Research Administrative Review, the survey of veterans on issues of genomics medicine research, and the concerns raised by Cooperative Study 519. All of these issues will be covered in greater detail during the course of the meeting.

Electronic Review Update – Dr. Goldberg:

- A new page in the ORD intranet has been created
- Instructions, guidance documents, and necessary forms/templates can be found here
- <http://vaww.research.va.gov/funding/electronic-submission.cfm>
- RFAs for electronic submission of Merit Review proposals will be posted on a separate intranet page, distinct from information on paper-based solicitations
- <http://vaww.research.va.gov/funding/rfa.cfm>
- PureEdge Reader and PDF Converter Software will be required for the September submission
- Grants.gov and eRA Commons are working on the transition to replace PureEdge with Adobe Acrobat Reader 8
- All merit Review for the September deadline will be submitted as “New” proposals, even if it is a resubmission or a previously reviewed application or a renewal of a previously funded program
- eRA Commons will generate a grant number for all Merit Review applications
- 4 new RFAs have been posted on Grants.gov and the ORD Intranet
- There will be “standing” RFAs for investigator initiated Merit Review proposals
- Additional RFAs will be issued for special solicitations

Research Presentation – George Wittenberg, MD, PhD,

Dr. Wittenberg described his research activities to measure changes in the brain after stroke. He also spoke about the Excite Trial, a multisite study of sub acute stroke patients using Constraint Induced Therapy (CIT). The study showed that patients provided CIT had a two-fold improvement in functioning. Dr. Wittenberg then described recent activities using multiple types of robots to provide graded assistance to patients with limited use of their ankle or wrist. The robots incorporate games which the patients enjoy and ensure that the movements are performed correctly. Dr. Wittenberg concluded with an overview of The Maryland Center for Exercise and Robotics in Disability and Aging.

Cooperative Study 519 – Dr. Kupersmith:

Dr. Kupersmith described Cooperative Study 519 and a June 17 Washington Times article that described an incident with a veteran. The article resulted in a number of letters from Congress and an Inspector General report on the Washington DC facility where the veteran was enrolled in CSP 519. CSP 519 was not a drug study and was not funded by Pfizer. Dr. Kupersmith described the history of the drug and a series of communications between FDA and VA, and between VA Pharmacy Benefits Management (PBM) and VA clinicians and VA researchers. The VA Secretary and VA's Office of Research Oversight (ORO) have been actively involved in this matter. NRAC members in discussion believe that VA acted appropriately and timely in this matter and suggested that a letter of support for VA research and ORD's efforts be sent to the Secretary.

Administrative Review - Sandi Isaacson:

Ms. Isaacson described the Administrative Review process, Sub-Committees and membership. Dr. Kupersmith noted that this is the first time that we have brought local VA administrators and researchers together to look at local governance of the research program. There is a lot of interest in this topic and a lot of enthusiasm. Group will address issues of the function and responsibilities of the R&D Committee, ACOS Office and Medical Center Director.

BLR&D and CSR&D Update – Dr. O'Leary

Dr. O'Leary described the most recent merit review cycle. The programs received 466 proposals of which 108 (23%) were selected for funding. Reviews were conducted by 21 subcommittees. With respect to the research career scientist program, the program supports 131 awardees.

Dr. O'Leary described the William S Middleton Award, BLR&D's highest award to VA investigators for pioneering and outstanding scientific achievement in the biomedical and behavioral sciences. The award was presented in May 2008 to Robert Freedman, MD from Denver and Daryl Granner, MD from Nashville. Dr. Freedman was recognized for his pioneering contributions to causes and treatment of Schizophrenia while Dr. Granner was honored for his seminal discovery of the gene regulation function of insulin.

HSR&D Update – Dr. Eisen:

Dr. Eisen spoke of a recent initiative to create a Center for Scientific Computing (CSC). The goal is to make more data available to investigators while enhancing data security and privacy. Another initiative is the Consortium for Healthcare Informatics Research (CHIR). The goal is to create a virtual informatics research consortium to extract, cleanse, reformat, de-identify text, and prepare text for data mining. A third initiative is Provider Education to Improve Patient Outcomes. The goal of this initiative is to determine the impact of provider education on patient outcomes, facilitate collaboration with the Office of Academic Affiliations and Employee Education, develop education measurement tools, and develop and evaluate alternative education methodologies.

Research Week in Washington – Dr. Kupersmith:

Dr. Kupersmith described the recent Research Week event at VA Central Office. The work of a number of VA investigators was presented including the work of recent Middleton award winners. Susan Dentzer, the editor of Health Affairs, also spoke. The VA Secretary, the Under Secretary for Health, and Dr. Kupersmith also made presentations. Bob Feller, a WWII veteran and Baseball Hall of Famer, was a featured presenter. Dr. Kupersmith acknowledged the contributions of Ms. Gina Clemons to the success of this program. Plans are underway for next year's program.

VA Central IRB and 2009 Local Accountability for Research Meeting – Dr. Cates:

Accreditation

- 112 of 115 VA facilities have submitted AAHRPP applications & will have been reviewed by AAHRPP Council by the end of CY 2008
- Accreditation status
 - 57 Full
 - 1 Full pending affiliate
 - 6 Qualified
 - 26 Pending

VA Central IRB

- 20 members including 2 co-chairs
- 5 meetings for training & organizational issues & mock protocol review
- Webinars – overview of VA Central IRB & walk through process
 - 3 for VA facilities (33 sites)
 - 1 for investigators
- 1st protocol review July 25 or August 22

2009 ORD Local Accountability for Research Meeting

- January 13-14, 2009
- Marriott Baltimore Waterfront
- Attendees will include
 - 5 representatives from each of 115 VA facilities with an FWA (no substitutions)
 - Medical Center Director (MCD)
 - Chief of Staff
 - ACOS/R&D
 - AO/R&D
 - Research Compliance Officer (RCO)
 - Select VISN representatives
 - ORO staff

Evaluation of Career Development Program (CDP) – Dr. Eisen:

The goal of this initiative is to evaluate the impact of CDP on recruitment, retention, investigator careers and research contribution. An observational study is proposed comparing three groups: those offered and accepted CDP awards, those offered and not accepted, and those not offered an award. Investigators will look at groups within and across research services. The study will utilize existing data as well as questionnaires, interviews and focus groups.

RR&D Update – Dr. Selzer:

Dr. Selzer addressed a number of new initiatives including the recent SOTA conference on TBI, and solicitations for Centers of Excellence and Research Enhancement Award Programs in the areas of TBI, regenerative medicine, social reintegration and vocational rehabilitation.

Survey of Veterans on Genomic Medicine Program – Dr. Przygodzki

A survey was conducted in spring 2008 involving 931 veterans who receive care at VA. Survey had 80 items. Preliminary results: There is a strong positive correlation between willingness to participate in genomics research and satisfaction with VA care and altruistic behavior (e.g., blood donor). Overall 83% said the VA should have a genomics medicine program. 71% said that they would participate in such a program. Participation was associated with attitudes about research, attitudes about helping others, curiosity about genetics, satisfaction with VA and demographics.

Meeting was adjourned at 1:30 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate and complete record of the substance of the meeting.

Jay A. Freedman, PhD
Designated Federal Officer
National Research Advisory Council

Marie A. Bernard, MD
Chair
National Research Advisory Council

These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.